REMARKS

The present claims are claims 1, 2, 4-7, 9-13 and 15-20. Claim 1 has been amended to incorporate limitations from claim 14. The amendment to claim 19 finds support at page 12, first full paragraph (of the substitute copy of the specification filed on September 8, 2000). Favorable reconsideration of this application is respectfully requested.

Claims 1-6, 8, 9 and 12-20 were rejected under 35 USC 112, first paragraph, based on several specific objections. It is believed the present amendments obviate this rejection, and the Examiner's helpful comments are appreciated.

Claims 8, 12 and 13 were rejected under 35 USC 112, second paragraph, as indefinite. Again, the present amendments obviate this rejection, and the Examiner's helpful comments are appreciated.

Applicant appreciates the notation of allowable subject matter in original claims 14, 19 and 20. As claim 1 incorporates the subject matter of claim 14, it is believed that claim 1 and subsequent dependent claims 2, 4-6 and 15-18 are allowable for reasons of record, so these claims are not specifically discussed in the following rejections based on prior art.

Claims 1, 3-6 and 15-18 were rejected under 35 USC 102(b) as anticipated by Chang et al. (US 5,712,327). Reconsideration is requested.

The presently claimed invention relates to methods for improving the wettability of a silicone-containing medical device, such as a contact lens. As discussed in the specification at page 1, silicone-containing devices tend to be relatively hydrophobic, thus rendering the surface of the device relatively non-wettable with a high affinity for lipids. Various approaches to improve wettability of such devices have been proposed in the past, for example, methods that involved some type of plasma treatment or corona discharge treatment of the device surface, or methods that required some type of coupling agent to link a wetting agent to the device surface. The present invention provides much more convenient "solution treatments" that do not require the plasma or corona discharge treatment, or such coupling agents. Specifically, the wetting agent forms a complex with the hydrophilic monomer from which the device is formed, via hydrogen bonding between this agent and monomer, at the surface of the device.

Chang et al., at column 4, line 46 to column 5, line 20, discloses two methods for increasing the proportion of hydroxy acrylic monomer (HAM) units at a contact lens surface, as compared to the HAM units in the body of the lens. Please see column 3, line 65 to column 4,

line 37. According to the first method, the lens surface is reacted with a polyol (of the formula $R_1(OH)_n$, such as glycerin) in the presence of a base or acid, to effect a transesterification. In contrast, the present invention does not rely on any such transesterification reaction of a polyol, and independent claim 7 defines wetting agents other than such polyols. According to the second method, the lens is treated with a HAM, such as HEMA or GMA, so as to graft, deposit or coat the lens surface with the HAM, preferably by radiation-induced reactions. In contrast, the present invention does not rely on any such radiation-induced grafting, and independent claim 7 defines wetting agents other than HEMA or GMA.

Claims 1-13 and 15-18 were rejected under 35 USC 102(b) as anticipated by Lai et al. (US 5,726,733). Reconsideration is requested.

Lai et al. discloses a method for improving surface wettability of a contact lens, where a surface of the lens is contacted with a solution including a hydrophilic monomer, and the solution is heated while in contact with the lens surface to effect polymerization of the hydrophilic monomer. The treating solution includes a hydrophilic, unreacted monomer that is then thermally polymerized to bond to the lens surface. In contrast, the present invention does not rely on any such thermal polymerization of a wetting agent, and independent claim 7 defines treatment of the device with a polymer or copolymer of (meth)acrylic acid (i.e., an already polymerized polymer or copolymer, not an unpolymerized monomer as in Lai et al.)

Claims 4-6 were rejected under 35 USC 103(a) as unpatentable over Lai et al. (US 5,726,733) as applied to claim 1 above, and further in view of Kunzler et al. (US 5,710,302). The amendment of claim 1, from which claims 4-6 depend, obviates this rejection.

Claims 1-13 and 15-18 were rejected under 35 USC 103(a) as unpatentable over Kunzler et al. (US 5,710,302) in view of Bowers et al. (US 5,705,583). Reconsideration is requested.

Kunzler et al. is relied on for disclosing various silicone hydrogel contact lenses. It is noted that the presently claimed methods are applicable to the contact lenses disclosed in this reference. Kunzler et al. does not suggest any such lens-treatment methods.

Regarding Bowers et al., the rejection states that:

> Bowers et al. teaches a process of binding a polymer to a surface by covalent bonding, specifically to render the surfaces biocompatible in column 1, lines 1-42.

As discussed and pointed out above, the present invention does not involve covalent bonding of the wetting agent, but rather, a hydrogen bonding mechanism between the recited wetting agent and the hydrophilic monomer used to form the bulk device, at the surface of the device. However, Bowers et al. discloses mechanisms other than covalent bonding, so each of the main embodiments disclosed by Bowers et al. is addressed below.

A first embodiment of Bowers et al. is described at column 3, line 48 to column 4, line 47. This embodiment is designed for coating of a hydrophobic surface (column 3, line 49, noting the presently claimed invention is applicable for coating of hydrophobic surfaces) and relies on physisorption at the hydrophobic surface, i.e., absorbtion without formation of a covalent interaction (column 3, line 59). However, this embodiment involves the presence of alkyl groups or 6 or more carbons, or fluoroalkyl groups (optionally containing ether linkages, double bonds or triple bonds) which are used as the pendant groups capable of binding the polymer to the surface. In contrast, independent claims 7 defines treatment methods where neither the hydrophilic monomer or the wetting agent has such alkyl or fluoroalkyl pendant groups.

A second embodiment of Bowers et al. is described at column 4, line 48 to column 5, line 14. This embodiment is designed for coating of a hydrophilic surface, whereas the presently claimed invention is designed for hydrophobic, silicone-containing devices; additionally, this embodiment of the reference involves covalently binding the polymer to the surface, whereas the presently claimed invention does not does not involve covalent bonding of the wetting agent, as pointed out above. Please see, especially, column 4, lines 48-51 of Bowers et al.

A third embodiment of Bowers et al. is described at column 5, lines 15 to 48. This embodiment is designed for coating of a surface bearing an ionic charge, where the polymer used to coat the surface also has ionic groups, so as to provide an ionic interaction between the ionic surface and the ionic polymer groups. Please see, especially, column 5, lines 15-18 and lines 44-48. In contrast, the presently claimed invention does not involve any such ionic interactions.

Accordingly, withdrawal of this rejection is respectfully requested.

A favorable action in the form of a Notice of Allowance is respectfully requested. The Examiner is invited to contact the undersigned to resolve any remaining issues.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

(The following page and line numbers refer to the substitute copy of the specification filed on September 8, 2000.)

The paragraph beginning at page 3, line 22, has been amended as follows:

(b) contacting a surface of the medical device with a solution including a polymer or copolymer of (meth)acrylic acid, whereby the polymer or copolymers of ~~meth(acrylic)~~ (meth)acrylic acid forms a complex with the hydrophilic monomer on the contact lens surface without a surface oxidation treatment step and without the addition of a coupling agent.

The paragraph beginning at page 5, line 17, has been amended as follows:

Surface coating materials useful in the present invention include P(vinylpyrrolidinone(VP)-co-acrylic acid(AA)), P(methylvinylether-alt-maleic acid), P(acrylic acid-graft-ethyleneoxide), P(acrylic acid-co-methacrylic acid), P(acrylamide-co-AA), ~~P(acrylamide-co-AA),~~ P(AA-co-maleic), and P(butadiene-maleic acid).

The paragraph beginning at page 12, line 25, has been amended as follows:

Solvents useful in the surface treatment (contacting) step of the present invention include solvents that readily solubilize proton donating ~~solubes~~ solutes such as carboxylic acids, sulfonic acids, fumaric acid, maleic acids, anhydrides such as maleic anhydride and functionalized alcohols such as vinyl alcohol. Preferred solvents include tetrahydrofuran (THF), acetonitrile, N,N-dimethyl formamide (DMF), and water. The most preferred solvent is water.

In the claims:

Claims 3, 8 and 14 have been canceled.

Claim 1 has been amended as follows:

1. (amended) A method for improving the wettability of a medical device, comprising the steps of:

(a) providing a medical device formed from a monomer mixture comprising a hydrophilic monomer and a silicone-containing monomer, wherein said medical device has not been subjected to a surface oxidation treatment;

(b) contacting a surface of the medical device with a wetting agent solution comprising ~~a~~ at least one proton-donating wetting agent selected from the group consisting of P(vinylpyrolidinone(VP)-co-acrylic acid(AA)), P(methylvinylether-alt-maleic acid), P(acrylic acid-graft-ethyleneoxide), P(acrylic acid-co-methacrylic acid), P(acrylamide-co-AA), P(acrylamide-co-AA), P(AA-co-maleic), and P(butadiene-maleic acid), whereby the wetting agent forms a complex with the hydrophilic monomer on the surface of the medical device in the absence of a surface oxidation treatment step and without the addition of a coupling agent.

Claim 4 has been amended as follows:

4. (amended) The method of claim 1, wherein the medical device comprises in bulk formula 5 to ~~75~~ 50 percent by weight of one or more silicone macromonomers and 5 to ~~75~~ 50 percent by weight of a hydrophilic monomer.

Claim 7 has been amended as follows:

7. (amended) A method for improving the wettability of a medical device, comprising the steps of:

(a) providing a medical device formed from a monomer mixture comprising a hydrophilic monomer and a silicone-containing monomer, wherein said medical device has not been subjected to a surface oxidation treatment;

(b) contacting a surface of the medical device with a solution comprising a wetting agent selected from the group consisting of polymers or copolymers of ~~meth(acrylic)~~ (meth)acrylic acid, whereby the wetting agent forms a complex with the hydrophilic monomer on the surface of the medical device in the absence of a surface oxidation treatment step and without the addition of a coupling agent.

Claim 9 has been amended as follows:

9. (amended) The method of claim 7, wherein the medical device comprises in bulk formula 5 to ~~75~~ 50 percent by weight of one or more silicone macromonomers and 5 to ~~75~~ 50 percent by weight of a hydrophilic monomer.

Claim 12 has been amended as follows:

12. (amended) The method of claim ~~1~~ 7 wherein said polymer or copolymer of (meth)acrylic acid is characterized by acid content of at least about ~~30~~ 40 mole percent

Claim 13 has been amended as follows:

13. (amended) The method of claim 12 wherein said polymer is characterized by acid content of at least about ~~40~~ 50 mole percent.

Claim 19 has been amended as follows:

19. (amended) A method for improving the wettability of a medical device comprising the steps of:

(a) providing a medical device formed from a monomer mixture comprising a silicone-containing monomer and at least one ~~other~~ hydrophilic monomer selected from the group consisting of ~~poly(n-vinyl pyrrolidone)~~ N-vinyl-2-pyrrolidone and ~~poly(dimethylacrylamide),~~ N,N-dimethylacrylamide, wherein said medical device has not been subjected to a surface oxidation treatment; and

(b) contacting a surface of the medical device with a solution comprising at least one selected from the group consisting of poly(acrylic acid) and poly(acrylic acid-co-acrylamide).